820-2 2025-02-13

For professional use only

PREP-NA-FET DNA Extraction Kit

INSTRUCTION FOR USE

EC REP

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REF P-027/2EU

VER 820-2.2025.02.13

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1. INTENDED USE

The **PREP-NA-FET DNA Extraction Kit** is intended for fetal DNA purification from peripheral blood of pregnant women. The obtained DNA sample will contain a small amount of maternal genomic DNA.

Indications for the use: the kit is an auxiliary agent for *in vitro* diagnostics (nucleic acids extraction for further PCR analysis) in clinical and diagnostic laboratory.

The application of the kit does not depend on population and demographic aspects. There are no contradictions for use of the **PREP-NA-FET DNA Extraction Kit.**

The **PREP-NA-FET DNA Extraction Kit** can be used in clinical and diagnostic laboratories of medical institutions and research practice.

Potential users: personnel qualified in molecular diagnostics methods and working in the clinical and diagnostic laboratory.

It is necessary to apply the kit only as directed in this instruction for use.

2. METHOD

The **PREP-NA-FET DNA Extraction Kit** offers an express DNA extraction method. The method is based on the release of nucleic acids under the action of a chaotropic agent with subsequent precipitation and clearing from impurities.

The **PREP-NA-FET DNA Extraction Kit** can be used in conjunction with medical devices designed for the analysis of nucleic acids by PCR. The obtaining NA preparation is ready for further analysis with PCR.

3. CONTENT

The **PREP-NA-FET DNA Extraction Kit** content is represented in Table 1.

Table 1. The **PREP-NA-FET DNA Extraction Kit** content for P-027/2EU

Reagent	Description	Total volume	Amount
Lysis solution[1]	Slightly foamy light blue or colorless transparent liquid	15 mL	1 vial
Precipitation buffer	Colorless transparent liquid	30 mL	1 vial
Wash solution No. 1	Colorless transparent liquid	25 mL	1 vial
Wash solution No. 2	Colorless transparent liquid	15 mL	1 vial
Dilution buffer	Colorless transparent liquid	2.8 mL (1.4 mL in each)	2 tubes
Deproteinization solution[2]	Colorless transparent liquid	1.0 mL	1 tube
Negative control	Colorless transparent liquid	13.5 mL	1 vial

All components are ready to use and do not require additional preparation for operation.

The kit is designed for DNA extraction from 50 analyzed samples (including negative controls).

[1] During storage is acceptable existence of a small amount of precipitate in lysis solution, which dissolves after heating the lysis solution on 65 °C.

[2] During storage is acceptable existence of a small amount of precipitate is acceptable in deproteinization solution, which does not affect the quality of extracted fet DNA.

4. REAGENTS AND EQUIPMENT REQUIRED BUT NOT PROVIDED

4.1. Specimen collection

- For blood collection: 4.5 mL Vacuette blood collection tubes with anticoagulant salt of EDTA at a final concentration of 2.0 mg/mL.

Please use only salt of EDTA as an anticoagulant, since other substances can provide PCR inhibition.

4.2. NA extraction

- Biological safety cabinet class II;
- Refrigerator;
- Vortex mixer;
- High speed centrifuge (RCF(g) at least 1,150) for 4.5 mL tubes;
- High speed centrifuge (RCF(g) at least 17,000) for 1.5 mL tubes;
- Solid-state thermostat (temperature range 65-98 °C);
- Freezing container, e.g. IsoFreeze 24x1.5/2 mL (SSI), or CoolRack M15, 15x1.5/2 mL (Biocision), or other analogous equipment;
- Electric laboratory aspirator with trap flask for the removal of supernatant;
- RNase and DNase free pipette tips for aspirator with trap flask;
- Single channel pipettes (dispensers covering 20-1000 µL volume range);
- RNase and DNase free filtered pipette tips (volume 20 µL, 200 µL, 1000 µL);
- Tube rack for 1.5 mL tubes;
- 1.5 mL tubes;
- Container for used pipette tips, tubes and other consumables;
- Powder-free surgical gloves;
- Disinfectant solution.

5. TRANSPORT AND STORAGE CONDITIONS

Expiry date – 12 months from the date of production.

The **PREP-NA-FET DNA Extraction Kit** must be transported in thermoboxes with ice packs by all types of roofed transport at temperatures inside the thermoboxes corresponding to storage conditions of the kit components.

It is allowed to transport the kit in thermoboxes with ice packs by all types of roofed transport at temperatures from 2 °C to 25 °C inside the thermoboxes, but for no longer than 5 days.

The kit transported with violation of temperature conditions must not be used.

All components of the **PREP-NA-FET DNA Extraction Kit** must be stored in a refrigerator or a cooling chamber at temperatures from 2 °C to 8 °C over the storage period.

A little precipitate is allowed in lysis solution during storage.

Shelf-life of the kit following the first opening of the primary container: the components of the kit must

be stored at temperatures from 2 °C to 8 °C over the storage period.

The kit stored under undue regime must not be used.

An expired **PREP-NA-FET DNA Extraction Kit** must not be used.

We strongly recommend to follow the given instructions in order to obtain accurate and reliable results.

The conformity of the **PREP-NA-FET DNA Extraction Kit** to the prescribed technical requirements is subject to compliance of storage, transportation and handling conditions recommended by manufacturer.

Contact our official representative in EU by quality issues of the **PREP-NA-FET DNA Extraction Kit**

6. WARNINGS AND PRECAUTIONS

Only personnel trained in the methods of molecular diagnostics and the rules of work in the clinical and diagnostic laboratory are allowed to work with the kit.

Handle and dispose all biological samples, reagents and materials used to carry out the assay as if they were able to transmit infective agents. The samples must be exclusively employed for certain type of analysis. Samples must be handled under a laminar flow hood. Tubes containing different samples must never be opened at the same time. Pipettes used to handle samples must be exclusively employed for this specific purpose. The pipettes must be of the positive dispensation type or be used with aerosol filter tips. The tips employed must be sterile, free from the DNases and RNases, free from DNA and RNA. The reagents must be handled under a laminar flow hood. The reagents required for amplification must be prepared in such a way that they can be used in a single session. Pipettes used to handle reagents must be exclusively employed for this specific purpose. The pipettes must be of the positive dispensation type or be used with aerosol filter tips. The tips employed must be sterile, free from the DNases and RNases, free from DNA and RNA. Avoid direct contact with the biological samples reagents and materials used to carry out the assay. Wear powder-free surgical gloves. Wear protective clothing (work clothes and personal protective equipment) working with microorganisms classified as particularly pathogenic. The protective clothing and personal protective equipment must comply with the work to be performed and health and safety requirements. Avoid producing spills or aerosol. Any material being exposed to biological samples must be treated for at least 30 minutes with disinfecting solution or autoclaved for 1 hour at 121 °C before disposal.

Molecular biology procedures, such as nucleic acids extraction, reverse transcription, PCR-amplification and detection require qualified staff to avoid the risk of erroneous results, especially due to the degradation of nucleic acids contained in the samples or sample contamination by amplification products.

All the liquid solutions are designed for single use and can not be used more than once in amplification reactions. Plastic tubes do not contain phthalates. Do not breathe gas/fumes/vapor/spray produced by the components of the kit. Do not eat/drink components of the kit. Avoid contact with eyes. Only use the reagents provided in the kit and those recommended by manufacturer. Do not mix reagents from different batches. Do not use reagents from third party manufacturers' kits. All laboratory equipment, including pipettes, test tube racks, laboratory glassware, lab coats, bouffant caps, etc., as well as reagents should be strictly stationary. It is not allowed to move them from one room to another. Equip separate areas for the extraction/preparation of amplification reactions and for the amplification/detection of amplification products. Never introduce an amplification product in the area designed for extraction/preparation of amplification reactions. Wear lab coats, gloves and tools, which are exclusively employed for the extraction/preparation of the amplification reaction and for the amplification/detection of the amplification products. Never transfer lab coats, gloves and tools from the area designed for amplification/detection of the amplification products to the area designed for extraction/preparation of amplification reactions. Wear lab coats, gloves and tools, which are exclusively employed for the extraction/preparation of the amplification reaction and for the amplification/detection of the amplification products. Never transfer lab coats, gloves and tools from the area designed for amplification/detection of the amplification products to the area designed for extraction/preparation of amplification reactions. Remove waste materials (tubes, tips) only in a special closed container containing

a disinfectant solution. Work surfaces, as well as rooms where NA extraction and PCR are performed, must be irradiated with bactericidal irradiators for 30 minutes before and after the work.

Waste materials are disposed of in accordance with local and national standards. All surfaces in the laboratory (work tables, test tube racks, equipment, etc.) must be treated daily with disinfecting solution.

Emergency actions

Eye Contact: If any component of this kit enters the eyes, wash eyes gently under potable running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occurs, obtain medical attention.

Skin Contact: If any component of this kit contacts the skin and causes discomfort, remove any contaminated clothing. Wash affected area with plenty of soap and water. If pain or irritation occurs, obtain medical attention.

Ingestion: If any component of this kit is ingested, wash mouth out with water. If irritation or discomfort occurs, obtain medical attention.

Do not use the kit:

- When the transportation and storage conditions are breached;
- When the reagents' appearance does not respond to the kit passport;
- When the kit components packaging is breached;
- After the expiry date provided.

Significant health effects are **NOT** anticipated from routine use of this kit when adhering to the instructions listed in the current manual.

7. SAMPLES

Peripheral blood is used as a sample.

Sample collection

The required blood volume is 4.0-4.5 mL. Peripheral blood sampling is carried out in vacuum plastic tubes, for example 4.5 mL Vacuette tubes containing ethylenediaminetetraacetic acid disodium salt (EDTA) at final concentration of 2.0 mg/mL as an anticoagulant. After taking the material, it is necessary to mix the blood with anticoagulant inverting the tube 2 – 3 times.

ATTENTION! It is not allowed to use heparin and sodium citrate as an anticoagulant.

Transportation and storage of the samples

It is recommended to start blood processing in the first two hours after sample intake.

When it is impossible to start blood processing in the first two hours, it is allowed to store blood at room temperature (from 18 °C to 25 °C) for no more than 4-8 hours.

Sample preparation

1 Centrifuge the tube with blood at RCF(g) 1150-2000 for 20 minutes at room temperatures from 18 °C to 25 °C.

2 Mark the required number of 1.5 mL tubes (two for each tested sample).

3 Transfer 900 µL of upper (plasma) fraction into the each marked tube. Do not touch the lower (cell) fraction.

ATTENTION! Only one tube is used for DNA extraction. The second tube may be frozen at minus 20 °C and, if needed, be used for re-extraction of DNA.

The obtained plasma is ready for fetal DNA extraction.

Storage of plasma at temperatures between 4 °C and 8 °C for not longer than 8 hours is accepted.

When planning the fetal DNA extraction on the next day or later, the tubes with the plasma should be frozen at minus 20 °C. Frozen plasma can be stored for up to 3 months. One of two tubes from each sample must be thawed at room temperature before DNA extraction.

8. PROCEDURE

General recommendations

ATTENTION! Use RNase and DNase free filtered pipette tips.

The lysis solution can form the precipitate. Dissolve it at 65 °C for 10 minutes prior to use.

Keep the deproteinization solution at room temperature for 15-20 minutes, then vortex for 10-15 seconds and spin for 1-3 seconds prior to use.

ATTENTION! Existence of a small amount of precipitate is acceptable and does not affect the quality of deproteinization solution.

DNA extraction

8.1 Prepare the plasma samples for DNA extraction. Thaw at room temperature if needed.

8.2 Mark one 1.5 mL tube for "C-" and add 900 µL of "C-" into the prepared tube.

8.3 Add 18 µL of deproteinization solution into the each tube with plasma samples and "C-" tube.

ATTENTION! Deproteinization solution has a high viscosity, therefore it is necessary to take it by pipette tip for 3-5 seconds and applied to the tube wall (separate tip for each sample).

8.4 Close the tubes tightly, vortex for 10-20 seconds and spin for 1–3 seconds.

8.5 Thermostate for 5 minutes at 98 °C.

ATTENTION! Opening the tubes caps when heating is possible. It is recommended to use the tubes with snap caps (e.g. Eppendorf Safe-Lock Tubes) or programmable thermostats with clamp lid (e.g. "DNA-Technology" Gnom thermostat).

If specialized freezing rack is not used, prepare an ice bath. Ice bath consists of container which is filled with cold water and lamp ice. Tubes rack with open bottom is placed to the container. Ice mixture should not reach till the tubes caps about 5.0 mm.

8.6 Place the tubes to the freezing rack for 10 minutes.

ATTENTION! Tubes must be transferred to the freezing rack immediately after thermostating. Tubes storage is not permitted. It may lead to incorrect results.

8.7 Dry the tubes by a paper tissue. Centrifuge the tubes at RCF(g) 17000 for 25 minutes at room temperature.

8.8 Mark the required number of new 1.5 mL tubes considering the number of samples to be tested and negative control.

8.9 Take 300 µL of supernatant (300 µL of solution from "C-" tube) and put it in the corresponding marked tubes.

ATTENTION! If the volume of supernatant is less than 300 µL, but more than 100 µL, take the entire volume. If the volume of supernatant is less than 100 µL, incorrect carrying-out of previous DNA extraction stages is possible (incorrect storage of blood and plasma, violation of centrifugation speed and time rate,

failure of temperature regimes). In that case repeat the DNA extraction using the second tube with plasma or repeat the blood sampling.

8.10 Add 300 µL of the lysis solution into the each tube avoiding contact of the pipette tip with an edge of the tube. Close the tubes tightly.

8.11 Vortex the tubes for 3-5 seconds and spin for 30 seconds.

8.12 Incubate the tubes for 15 minutes at 65 °C, spin down the drops for 30 seconds.

8.13 Add 600 µL of the precipitation buffer. Close the tubes tightly and vortex them for 3–5 seconds.

ATTENTION! After adding of the precipitation buffer, keep the tubes in a horizontal position for 7-10 minutes. Vortex the tubes once during this period.

8.14 Centrifuge the tubes at RCF(g) 17000 for 15 minutes at room temperature.

8.15 Remove supernatant completely avoiding contact of the pipette tip with the precipitate. Use new tip for each sample.

8.16 Add 500 µL of the wash solution № 1 to the precipitate and vortex the tubes for 3-5 seconds.

8.17 Centrifuge the tubes at RCF(g) 17000 for 5 minutes at room temperature.

8.18 Remove supernatant completely avoiding contact of the pipette tip with the precipitate. Use new tip for each sample.

8.19 Add 300 µL of the wash solution № 2 to the precipitate and vortex the tubes for 3-5 seconds.

8.20 Centrifuge the tubes at 17000 x g for 5 minutes at room temperature.

8.21 Remove supernatant completely avoiding contact of the pipette tip with the precipitate. Use new tip for each sample.

8.22 Open the tubes and dry the precipitate at 65 °C for 1 minute.

8.23 Add 35 µL of the dilution buffer to the precipitate. Close the tubes and warm up at 65°C for 10 minutes. Vortex the tubes for 3-5 seconds.

8.24 Spin down the drops centrifugation at RCF(g) 17000 for 30 seconds at room temperature.

DNA preparation is ready for performing PCR.

DNA preparation can be stored at minus 20 °C for not longer than a month or at minus 70 °C for not longer than a year.

9. QUALITY CONTROL

“DNA-Technology Research&Production”, LLC declares that the abovementioned products meet the provision of the Regulation (EU) 2017/746 of the European parliament and of the Council of 5 April 2017. The quality control procedures performed in accordance with ISO 9001:2015 and ISO 13485:2016:

- observation of quality management in manufacturing of IVDR products;
- creation of values for customers;
- maintenance of the best service quality and customer management.

Contact our official representative in EU by quality issues of the **PREP-NA-FET DNA Extraction Kit**.

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10. KEY TO SYMBOLS

IVD	*In vitro* diagnostic medical device		Date of manufacture
	Temperature limit		Consult instructions for use
Σ	Contains sufficient for <n> tests	REF	Catalogue number
	Use-by date		Manufacturer
LOT	Batch code	VER	Version
EC REP	Authorized representative in the European Community		Caution
NON STERILE	Non-sterile		

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